

Message

From: McNally, Robert [McNally.Robert@epa.gov]
Sent: 7/15/2020 4:13:39 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: RE: Oxitec Florida Webinar

Did Florida chime in to correct Oxitec? What role did they play?

So, if no vote, what is the next step?

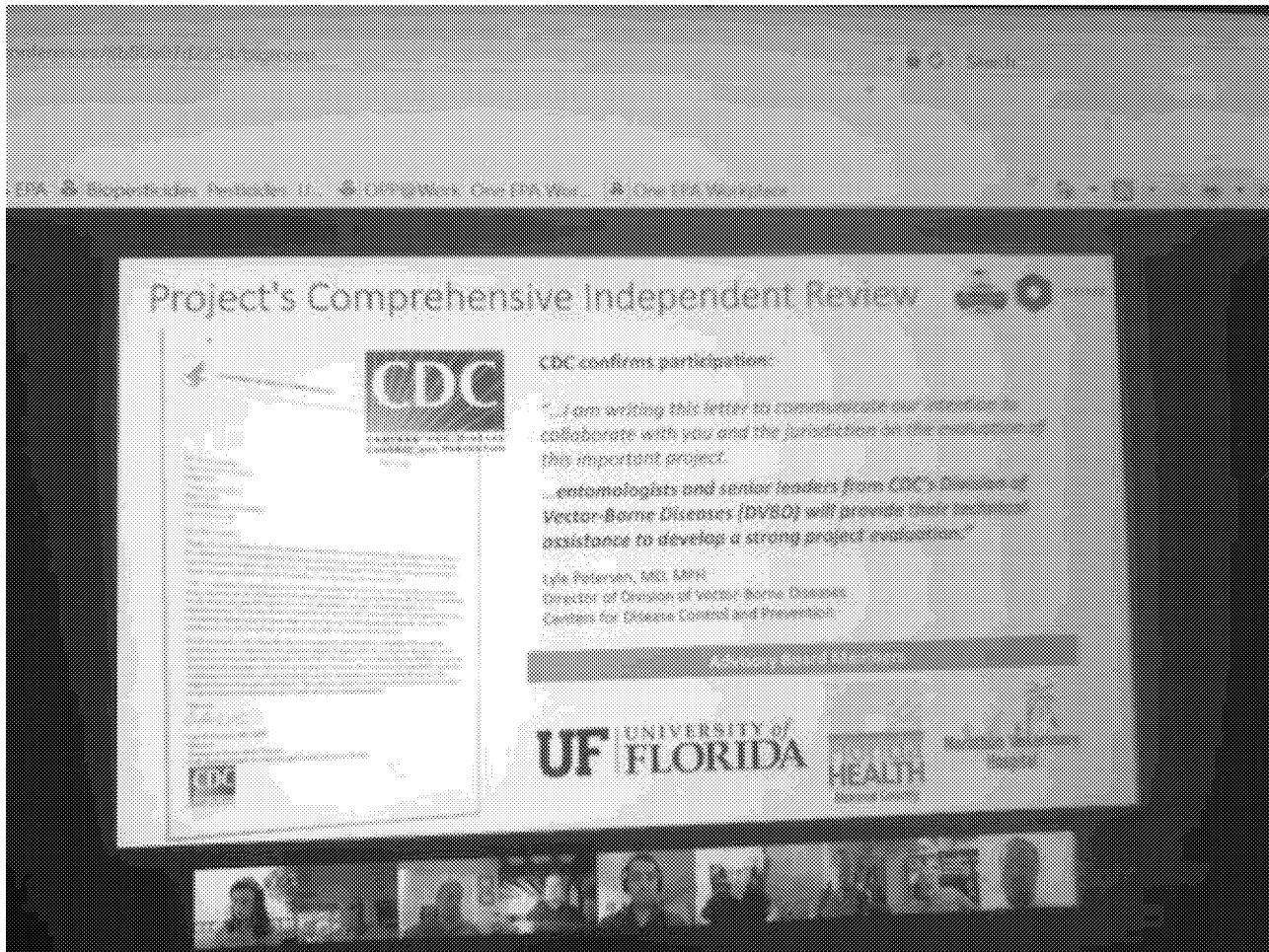
The Monroe County Board votes? If it passes, when does the release happen?

Any press there? Any press today?

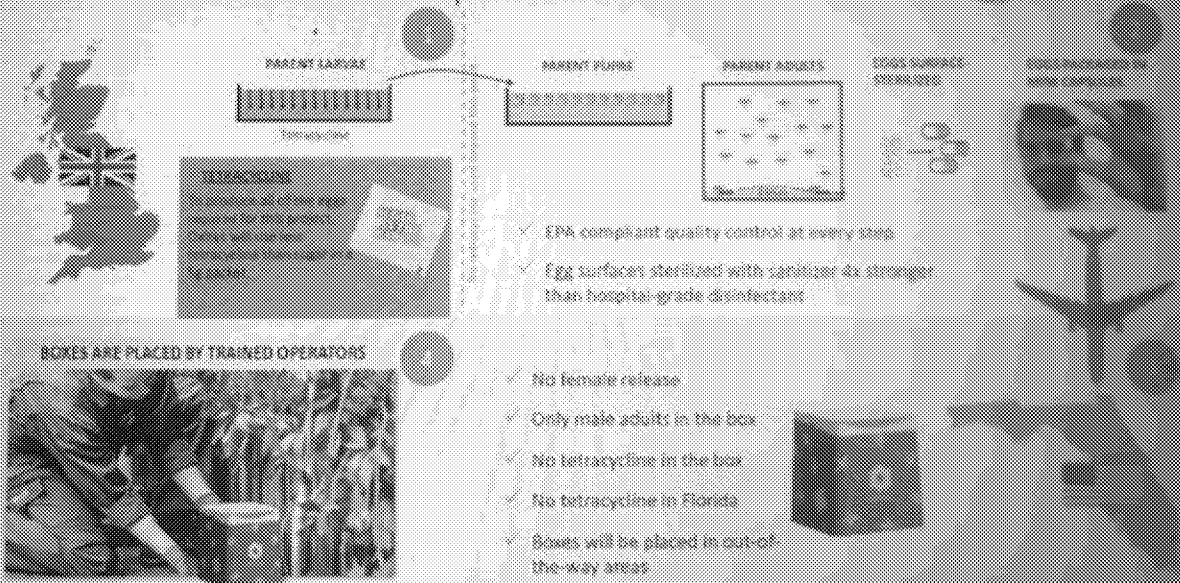
From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Wednesday, July 15, 2020 12:02 PM
To: McNally, Robert <McNally.Robert@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Moyer, Adam <moyer.adam@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
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Overall the session was quite good. I have a couple of questions I need to follow up on.

- Links to our risk assessment, response to comments, and issuance letter were provided.
- CDC is collaborating with Oxitec re: evaluation of data from the EUP.
- Oxitec seemed to indicate that no monitoring is required, but genetic resistance monitoring is required.
- When asked about tetracycline concerns, Oxitec did not bring up the required buffers and said it's an outside trial and mosquitoes move. They did mention our analysis and protocols (I think required by FDACS) to remove materials in the case of upcoming severe weather.
- Oxitec again promoted the benefit of moving insecticide susceptibility genes to native populations.
- Public exposure and informed consent was brought up and our response to comments document was cited since the EUP did not meet the standard of requiring informed consent and male mosquitoes don't bite.
- The mosquito control district mentioned that they are looking at effectiveness and cost when considering tools.
- The mosquito control district mentioned they are only concerned with *Aedes aegypti* for disease transmission concerns.
- A question was posed regarding efficacy and Oxitec incorrectly said that there was not an actual percentage control/suppression that would measure success, but the whole impact.
- Another referendum to voters is not planned.
- Most questions came from a few individuals. Barry Ray submitted lots of comments, but the forum focused on answering questions.
- Oxitec did not provide funds to the mosquito control district, but is also not charging them for the testing.
- Oxitec has already transformed *Aedes albopictus* (Asian Tiger mosquito) and *Anopheles gambiae* (African mosquito that spreads malaria) and these are on the shelf.
- A paper was brought up that indicated that global warming was increasing mutation in mosquitoes. Dr. Rey from UF said he was unaware of the article or journal, but certainly warmer climates could bring about more generations that could lead to more mutations.
- Some screenshots follow.



How Are OX5034 Mosquitoes Made?

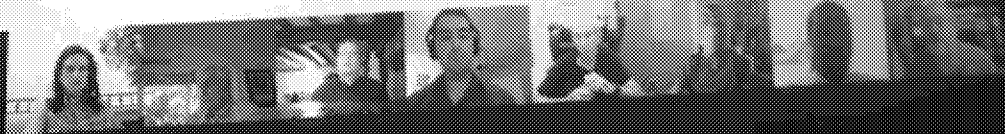
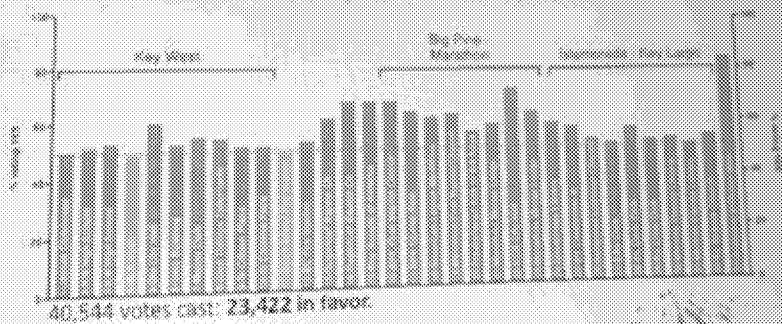


Successful 2016 Monroe County Referendum



"Are you in favor of the Florida Keys Mosquito Control District conducting an effectiveness trial in Monroe County, Florida, using genetically modified mosquitoes to suppress an invasive mosquito that carries West Nile virus?"

Oxley OM Mosquito Referendum Results Nov 2016

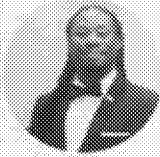


BigMarker Webinar Room


es Tools Help

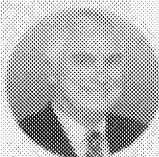
es Pesticides US EPA Biopesticides Pesticides 11 OPP@Work One EPA Wor One EPA Workplace

Independent Panelists




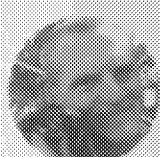
Dr. Oscar Alleyne
Chief of Programs and Services
National Association of County and City Health Officials (NACCHO)






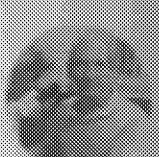
Bob Eadie
Administrator and Health Officer
Monroe County Department of Health
Member, Project Independent Advisory Board






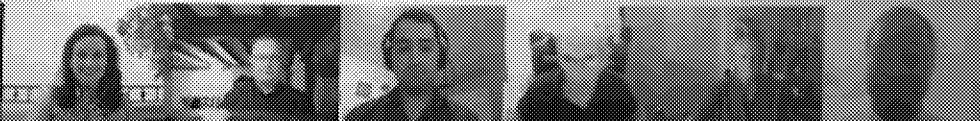
Dr. Douglas Mader
Marathon Veterinary Hospital
Fellow, Royal Society of Medicine
Member, Project Independent Advisory Board





Dr. Jorge Rey
Director and Professor
University of Florida - IFAS
Florida Medical Entomology Laboratory
Member, Project Independent Advisory Board



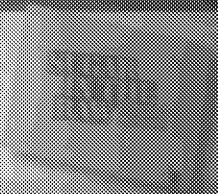


Use of Tetracycline: EPA Confirms Oxitec Mosquitoes Pose No Risk



Our technology introduces no hazards associated with tetracycline.

- Eggs shipped to Florida have never been in contact with tetracycline
- To produce all the eggs required for this project in the UK, Oxitec will use less tetracycline than sugar in a packet, equivalent to two human therapeutic courses
- Florida farmers use up to 88 million times more tetracycline to treat trees



EPA has concluded that *"there is negligible risk that testing of OX5034 mosquitoes would spread antibiotic resistant bacteria in the US environment"*

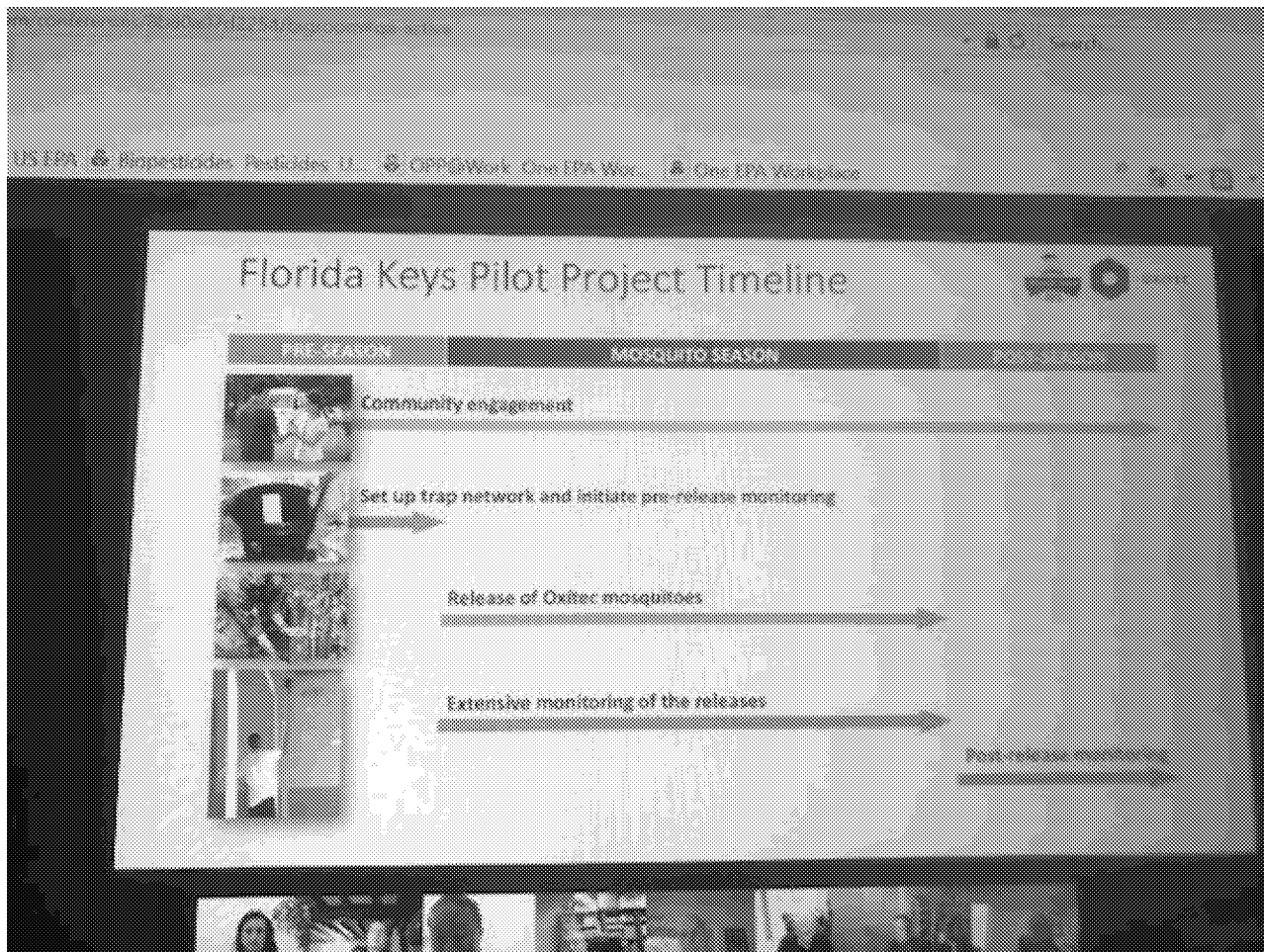
In the USA, every year:

- Doctors' offices and emergency departments prescribe about 47 million antibiotic courses for infections that don't need antibiotics (CDC)
- Nearly 4,000 tons supplied to livestock and pets (FDA)

In Florida:

- Up to 388,000 lbs of oxytetracycline approved for spraying each year on 300,000+ acres citrus trees since 2015 (EPA)
- Use of tetracyclines on farms and in human medicine is linked to resistant bacteria in waterways and coastal waters¹, and marine wildlife²

1. <https://www.epa.gov/pesticide-registration/oxitec-mosquitoes>
2. <https://www.epa.gov/pesticide-registration/oxitec-mosquitoes>



Biopesticides Pesticides U.S. & OPP@Work One EPA Workplace

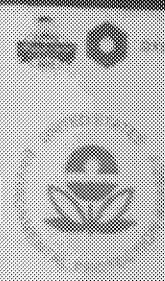
Overview of EPA's Review & Approval

Key Elements:

- 14-month in-depth process
- Exhaustive scientific review
- Risk assessment
- Multi-agency support
- Public comment responses


By the Numbers:

- 70+ documents submitted
- 25 commissioned studies
- 4,500+ pages, including 2,500+ pages of scientific peer-reviewed literature



Data Requirements Fulfilled by Oxitec (partial list)

Environmental Assessments:	Health Assessments:	Mosquito Characterization and Performance:	
• Fish	• Trait Penetration	• Insecticide Susceptibility	• Protein Stability
• Birds	• Oral Toxicity	• Trait Penetration	• Arbovirus Screening
• Mammals	• Inhalation Toxicity	• Tetracycline Response	• Integration Analysis
• Plants	• Ocular Toxicity	• Stability of Genetic Traits	• Complete 90%
• Aquatic Invertebrates	• Dermal Toxicity	• Trait Persistence	• Analytical Methodologies
• Insects	• Allergenicity	• Field Data (Brazil)	
• Endangered Species	• Vector Competence		



From: McNally, Robert <McNally.Robert@epa.gov>

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Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Moyer, Adam <moyer.adam@epa.gov>

Subject: Florida Session

Any takeaways you can share?